IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and KAI PHARMACEUTICALS, INC., Plaintiffs, v. MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS INC. and MSN LIFE SCIENCES PRIVATE LIMITED, Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Amgen Inc. ("Amgen") and KAI Pharmaceuticals, Inc. ("KAI") (collectively "Plaintiffs") by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendants MSN Laboratories Private Limited ("MSN Labs"), MSN Pharmaceuticals Inc. ("MSN Pharma"), and MSN Life Sciences Private Limited ("MSN Life") (collectively, "MSN") of Abbreviated New Drug Application ("ANDA") No. 215877 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Parsabiv® (etelcalcetide) injection for intravenous use at strengths of 2.5 mg/0.5 mL, 5 mg/mL, and 10 mg/2 mL ("MSN's Proposed ANDA Product") prior to the expiration of U.S. Patent Nos. 8,377,880 ("the '880 patent"), 8,999,932 ("the '932 patent"), 9,278,995 ("the '995 patent"), 9,701,712 ("the '712 patent"), 9,820,938 ("the '938 patent"), and 10,344,765 ("the '765 patent") (collectively, "the Asserted Patents"). MSN notified Plaintiffs that it had submitted this ANDA by a letter received April 8, 2021 ("Notice Letter"). Upon information and belief, MSN's Proposed ANDA Product will be

marketed as a competing product to Parsabiv® (etelcalcetide), a product developed by Plaintiffs for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

PARTIES

2. Plaintiff Amgen is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320.

3. Plaintiff KAI is a corporation organized and existing under the laws of Delaware, having a place of business at One Amgen Center Drive, Thousand Oaks, CA 91320. KAI is a wholly owned subsidiary of Amgen.

4. Upon information and belief, Defendant MSN Labs is a private limited company organized and existing under the laws of the Republic of India, having a place of business at MSN House, Plot No. C-24, Sanathnagar Industrial Estate, Hyderabad, Telangana 500018, India. Upon information and belief, MSN Labs is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries throughout the United States, including in Delaware.

5. Upon information and belief, Defendant MSN Pharma is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at 20 Duke Road, Piscataway, NJ 08854. Upon information and belief, MSN Pharma is a wholly owned subsidiary of MSN Labs. Upon information and belief, MSN Pharma is the designated U.S. agent for MSN Labs in accordance with 21 C.F.R. §§ 314.50(a)(5) and 314.94(a)(1) for ANDA No. 215877. Upon information and belief, MSN Pharma is in the business of, among other

things, manufacturing and selling generic versions of branded pharmaceutical products throughout the United States, including in Delaware.

6. Upon information and belief, Defendant MSN Life is a private limited company organized and existing under the laws of the Republic of India, having a place of business at Sy No. 21/A & 21AA, Mambapur, Gummadidala, Sangreddy, Telangana 502313, India. Upon information and belief, MSN Life is a wholly owned subsidiary of MSN Labs. Upon information and belief, MSN Life is the holder of FDA Drug Master File No. 35097 for MSN's Proposed ANDA Product. Upon information and belief, MSN Life is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products throughout the United States, including in Delaware.

7. Upon information and belief, MSN Labs, MSN Pharma, and MSN Life collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Upon further information and belief, MSN Labs, MSN Pharma, and MSN Life are agents of each other and/or operate in concert as integrated parts of the same business group.

8. Upon information and belief, MSN Labs, MSN Pharma, and MSN Life acted in concert to develop MSN's Proposed ANDA Product that is the subject of ANDA No. 215877 and to seek regulatory approval from the FDA to market and sell MSN's Proposed ANDA Product throughout the United States, including in Delaware.

9. Upon information and belief, MSN Labs, MSN Pharma, and MSN Life intend to act collaboratively to obtain approval for MSN's ANDA No. 215877, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import MSN's Proposed ANDA Product in the United States, including in Delaware.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over MSN Pharma because, on information and belief, MSN Pharma is a corporation organized and existing under the laws of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, MSN Pharma has consented to general jurisdiction in Delaware.

12. This Court has personal jurisdiction over MSN Labs and MSN Life because, *inter alia*, MSN Labs and MSN Life, themselves and through their affiliates and subsidiaries including MSN Pharma, have purposefully availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. On information and belief, MSN Labs and MSN Life, themselves and through their affiliates and subsidiaries including MSN Pharma, develop, manufacture, import, market, offer to sell, sell, and/or distribute a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transact business within Delaware relating to Plaintiffs' claims, and/or have engaged in systematic and continuous business contacts within Delaware.

13. In addition, this Court has personal jurisdiction over MSN Labs and MSN Life because, among other things, on information and belief: (1) MSN Labs, MSN Life, and their affiliate MSN Pharma submitted MSN's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product in the United States, including in Delaware; and (2) upon approval of MSN's ANDA, MSN Labs, MSN Life, and their affiliate MSN Pharma, themselves and through their affiliates and subsidiaries, will market, distribute, offer for sale, sell, and/or import MSN's Proposed ANDA Product in the United

States, including in Delaware, and will derive substantial revenue from the use or consumption of MSN's Proposed ANDA Product in Delaware. On information and belief, upon approval of MSN's ANDA, MSN's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware.

14. In addition, this Court has personal jurisdiction over MSN Labs and MSN Life because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Amgen and KAI, both Delaware corporations.

15. In addition, this Court has personal jurisdiction over MSN Labs and MSN Life because they regularly engage in patent litigation concerning MSN's ANDA products in this District, do not contest personal jurisdiction in this District, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Otsuka Pharmaceutical Co., Ltd. et al. v. MSN Laboratories Private Ltd.*, *MSN Pharmaceuticals Inc. and MSN Life Sciences Pvt. Ltd.*, C.A. No. 20-01428 (D. Del.); *Intercept Pharmaceuticals, Inc. et al. v. MSN Laboratories Private Ltd.*, *MSN Pharmaceuticals, Inc. and MSN Life Sciences Private Ltd.*, C.A. No. 20-01214 (D. Del.).

16. In addition, to the extent personal jurisdiction does not exist over MSN Labs and MSN Life in Delaware, this Court has personal jurisdiction over them under Federal Rule of Civil Procedure 4(k)(2) because MSN Labs and MSN Life are not subject to jurisdiction in any state's courts of general jurisdiction and exercising jurisdiction over them is consistent with the United States Constitution and laws.

17. For at least the above reasons, it would not be unfair or unreasonable for MSN Labs, MSN Life, and MSN Pharma to litigate this action in this District, and MSN Labs, MSN Life, and MSN Pharma are subject to personal jurisdiction in this District.

18. Venue is proper in this Court under 28 U.S.C. § 1391(c) with respect to MSN Labs at least because, on information and belief, MSN Labs is a foreign corporation that may be sued in any judicial district.

19. Venue is proper in this Court under 28 U.S.C. § 1391(c) with respect to MSN Life at least because, on information and belief, MSN Life is a foreign corporation that may be sued in any judicial district.

20. Venue is proper in this Court under 28 U.S.C. § 1400(b) with respect to MSN Pharma at least because, on information and belief, MSN Pharma is a corporation organized and existing under the laws of Delaware and therefore resides in Delaware for purposes of venue.

BACKGROUND

PARSABIV® (ETELCALCETIDE)

21. On February 7, 2017, the FDA granted approval to market Parsabiv® (etelcalcetide) for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis.

22. The active pharmaceutical ingredient in Parsabiv® is etelcalcetide, which was invented by scientists at KAI and developed by KAI and Amgen. Etelcalcetide is a synthetic peptide calcium-sensing receptor agonist. It is a calcimimetic agent that allosterically modulates the calcium-sensing receptor ("CaSR"). Etelcalcetide binds to the CaSR and enhances activation of the receptor by extracellular calcium. Activation of the CaSR on parathyroid chief cells decreases parathyroid hormone ("PTH") secretion.

23. Parsabiv® (etelcalcetide) is FDA approved for intravenous injection. It is FDA approved as a sterile, preservative-free, ready-to-use clear and colorless solution in a single-dose vial containing 5 mg/mL of etelcalcetide. Each vial contains 2.5, 5, or 10 mg etelcalcetide. Each vial is formulated with 0.85% weight/volume sodium chloride, 10 mM succinic acid, and adjusted to pH 3.3 with sodium hydroxide and/or hydrochloric acid.

24. Amgen, itself or through a subsidiary, markets Parsabiv® (etelcalcetide) in the United States pursuant to approved New Drug Application ("NDA") No. 208325.

25. KAI, a wholly owned subsidiary of Amgen, is the holder of approved NDA No. 208325 for Parsabiv® (etelcalcetide).

26. The Asserted Patents are listed for NDA No. 208325 for Parsabiv® (etelcalcetide) in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

27. The '880 patent, titled "Therapeutic Agents for Reducing Parathyroid Hormone Levels," was duly and legally issued on February 19, 2013. A copy of the '880 patent is attached as Exhibit A.

28. Plaintiffs own and have rights to the '880 patent.

29. There is an actual case or controversy between the parties regarding MSN's liability for its infringement of the '880 patent.

30. The '932 patent, titled "Therapeutic Agents for Reducing Parathyroid Hormone Levels," was duly and legally issued on April 7, 2015. A copy of the '932 patent is attached as Exhibit B.

31. Plaintiffs own and have rights to the '932 patent.

32. There is an actual case or controversy between the parties regarding MSN's liability for its infringement of the '932 patent.

33. The '995 patent, titled "Therapeutic Agents for Reducing Parathyroid Hormone Levels," was duly and legally issued on March 8, 2016. A copy of the '995 patent is attached as Exhibit C.

34. Plaintiffs own and have rights to the '995 patent.

35. There is an actual case or controversy between the parties regarding MSN's liability for its infringement of the '995 patent.

36. The '712 patent, titled "Therapeutic Agents for Reducing Parathyroid Hormone Levels," was duly and legally issued on July 11, 2017. A copy of the '712 patent is attached as Exhibit D.

37. Plaintiffs own and have rights to the '712 patent.

38. There is an actual case or controversy between the parties regarding MSN's liability for its infringement of the '712 patent.

39. The '938 patent, titled "Stable Liquid Formulation of AMG 416 (Etelcalcetide)," was duly and legally issued on November 21, 2017. A copy of the '938 patent is attached as Exhibit E.

40. Plaintiffs own and have rights to the '938 patent.

41. There is an actual case or controversy between the parties regarding MSN's liability for its infringement of the '938 patent.

42. The '765 patent, titled "Stable Liquid Formulation of AMG 416 (Etelcalcetide)," was duly and legally issued on July 9, 2019. A copy of the '765 patent is attached as Exhibit F.

43. Plaintiffs own and have rights to the '765 patent.

44. There is an actual case or controversy between the parties regarding MSN's liability for its infringement of the '765 patent.

MSN'S ANDA

45. On April 8, 2021, Plaintiffs received MSN's Notice Letter, which informed Plaintiffs that MSN seeks through ANDA No. 215877 approval to engage in the commercial manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product prior to the expiration of the Asserted Patents. According to the Notice Letter, included within ANDA No. 215877 is a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product.

46. This action is being filed within 45 days of Plaintiffs' receipt of MSN's Notice Letter.

47. MSN was aware of the Asserted Patents when ANDA No. 215877 was filed with a Paragraph IV Certification.

48. On information and belief, etelcalcetide is the active ingredient in MSN's Proposed ANDA Product. On information and belief, MSN's Proposed ANDA Product is a pharmaceutical formulation comprising etelcalcetide in an aqueous solution having a pH of 2.0 to 5.0.

49. On information and belief, ANDA No. 215877 refers to and relies upon the NDA for Parsabiv® (etelcalcetide) and contains data that, according to MSN, demonstrate bioequivalence of MSN's Proposed ANDA Product and Parsabiv® (etelcalcetide), *see* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7), or MSN has sought a waiver of the requirement to demonstrate bioequivalence of MSN's Proposed ANDA Product and Parsabiv® (etelcalcetide).

50. On information and belief, MSN intends to have healthcare providers use MSN's Proposed ANDA Product, if approved, as set forth in MSN's Proposed ANDA Product label. On information and belief, MSN's Proposed ANDA Product label will instruct healthcare providers to prescribe MSN's Proposed ANDA Product in the manner set forth in the label.

COUNT I
(Infringement of the '880 Patent)

51. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

52. Claim 1 of the '880 patent covers "[a] compound comprising Ac-c(C)arrrar-NH_2 (SEQ ID NO:3) [etelcalcetide]."

53. Upon information and belief, MSN's Proposed ANDA Product is covered by one or more claims of the '880 patent, including at least claim 1, because it contains etelcalcetide.

54. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, will infringe one or more claims of the '880 patent, including at least claim 1, either literally or under the doctrine of equivalents.

55. Upon information and belief, MSN filed as part of ANDA No. 215877 a Paragraph IV Certification, asserting that the claims of the '880 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product.

56. MSN did not contend in its Notice Letter that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe the claims of the '880 patent.

57. MSN has no reasonable basis to believe that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe one or more valid claims of the '880 patent.

58. The purpose of filing ANDA No. 215877 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product prior to the expiration of the '880 patent.

59. MSN's submission of ANDA No. 215877 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product prior to the expiration of the '880 patent is an act of infringement of the '880 patent under 35 U.S.C. § 271(e)(2)(A).

60. Upon information and belief, MSN intends to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto, *i.e.*, prior to the expiration of the '880 patent.

61. Upon information and belief, MSN has knowledge of the '880 patent at least because the '880 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, MSN continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto.

62. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '880 patent when ANDA No. 215877 and any amendments thereto are

approved, and will do so with specific intent to induce infringement of the '880 patent. Further upon information and belief, MSN plans and intends to, and will, do so immediately and imminently upon approval.

63. The foregoing actions by MSN constitute and/or will constitute infringement of the '880 patent and active inducement of infringement of the '880 patent, either literally or under the doctrine of equivalents.

64. Unless MSN is enjoined from infringing the '880 patent and actively inducing infringement of the '880 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '932 Patent)

65. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

66. Claim 1 of the '932 patent covers "[a] conjugate, comprising a peptide and a conjugating group, wherein the peptide comprises the amino acid sequence carrrar (SEQ ID NO:2), and wherein the peptide is linked to the conjugating group by a disulfide bond."

67. Claim 11 of the '932 patent covers "[a] method of treating secondary hyperparathyroidism (SHPT) in a subject, comprising administering to the subject a therapeutically effective amount of a conjugate comprising a peptide and a conjugating group, wherein the peptide comprises the amino acid sequence carrrar (SEQ ID NO:2), and wherein the peptide is linked to the conjugating group by a disulfide bond."

68. Upon information and belief, MSN's Proposed ANDA Product is covered by one or more claims of the '932 patent, including at least claims 1 and 11, because it contains etelcalcetide, which is a conjugate comprising a peptide and a conjugating group, wherein the peptide comprises the amino acid sequence carrrar and wherein the peptide is linked to the

conjugating group by a disulfide bond, and will be used in a method of treating secondary hyperparathyroidism.

69. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, will infringe one or more claims of the '932 patent, including at least claims 1 and 11, either literally or under the doctrine of equivalents.

70. Upon information and belief, MSN filed as part of ANDA No. 215877 a Paragraph IV Certification, asserting that the claims of the '932 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product.

71. MSN did not contend in its Notice Letter that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe claims 1-4, 6, 7, 9-12, 14, 16-19, 21, 23, and 24 of the '932 patent.

72. MSN has no reasonable basis to believe that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe one or more valid claims of the '932 patent.

73. The purpose of filing ANDA No. 215877 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product prior to the expiration of the '932 patent.

74. MSN's submission of ANDA No. 215877 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA

Product prior to the expiration of the '932 patent is an act of infringement of the '932 patent under 35 U.S.C. § 271(e)(2)(A).

75. Upon information and belief, MSN intends to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto, *i.e.*, prior to the expiration of the '932 patent.

76. Upon information and belief, MSN has knowledge of the '932 patent at least because the '932 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, MSN continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto.

77. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '932 patent when ANDA No. 215877 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '932 patent. Further upon information and belief, MSN plans and intends to, and will, do so immediately and imminently upon approval.

78. Upon information and belief, MSN knows that MSN's Proposed ANDA Product is especially made or adapted for use in infringing the '932 patent, and that MSN's Proposed ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, MSN plans and intends to, and will, contribute to infringement by others of the '932 patent immediately and imminently upon approval of ANDA No. 215877 and any amendments thereto.

79. The foregoing actions by MSN constitute and/or will constitute infringement of the ’932 patent, active inducement of infringement of the ’932 patent, and contribution to the infringement by others of the ’932 patent, either literally or under the doctrine of equivalents.

80. Unless MSN is enjoined from infringing the ’932 patent, actively inducing infringement of the ’932 patent, and contributing to infringement by others of the ’932 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III
(Infringement of the ’995 Patent)

81. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

82. Claim 1 of the ’995 patent covers “[a] compound comprising a peptide and a conjugating group, wherein the peptide comprises an amino acid sequence having the formula X_1-X_2-X_3-X_4-X_5-X_6-X_7 wherein X_1 is D-cysteine; X_2 is an amino acid selected from the group consisting of D-arginine and D-alanine; X_3 is D-arginine; X_4 is an amino acid selected from the group consisting of D-arginine and D-alanine; X_5 is D-arginine; X_6 is a non-cationic amino acid; X_7 is D-arginine; wherein when X_2 is D-arginine, X_4 is D-alanine and when X_2 is D-alanine, X_4 is D-arginine; and wherein the peptide X_1 residue is linked to the conjugating group by a disulfide bond.”

83. Upon information and belief, MSN’s Proposed ANDA Product is covered by one or more claims of the ’995 patent, including at least claim 1, because it contains etelcalcetide, which comprises a peptide and a conjugating group, wherein the peptide comprises an amino acid sequence having the formula X_1-X_2-X_3-X_4-X_5-X_6-X_7, wherein X_1 is D-cysteine; X_2 is D-alanine; X_3 is D-arginine; X_4 is D-arginine; X_5 is D-arginine; X_6 is a non-cationic amino acid; X_7 is D-arginine; and wherein the peptide X_1 residue is linked to the conjugating group by a disulfide bond.

84. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, will infringe one or more claims of the '995 patent, including at least claim 1, either literally or under the doctrine of equivalents.

85. Upon information and belief, MSN filed as part of ANDA No. 215877 a Paragraph IV Certification, asserting that the claims of the '995 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product.

86. MSN did not contend in its Notice Letter that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe claims 1-4, 11-13, 17, and 35 of the '995 patent.

87. MSN has no reasonable basis to believe that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe one or more valid claims of the '995 patent.

88. The purpose of filing ANDA No. 215877 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product prior to the expiration of the '995 patent.

89. MSN's submission of ANDA No. 215877 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product prior to the expiration of the '995 patent is an act of infringement of the '995 patent under 35 U.S.C. § 271(e)(2)(A).

90. Upon information and belief, MSN intends to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto, *i.e.*, prior to the expiration of the '995 patent.

91. Upon information and belief, MSN has knowledge of the '995 patent at least because the '995 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, MSN continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto.

92. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '995 patent when ANDA No. 215877 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '995 patent. Further upon information and belief, MSN plans and intends to, and will, do so immediately and imminently upon approval.

93. The foregoing actions by MSN constitute and/or will constitute infringement of the '995 patent and active inducement of infringement of the '995 patent, either literally or under the doctrine of equivalents.

94. Unless MSN is enjoined from infringing the '995 patent and actively inducing infringement of the '995 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV
(Infringement of the '712 Patent)

95. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

96. Claim 8 of the '712 patent covers "[a] pharmaceutically acceptable salt of a peptide comprising Ac-c(C)arrrar-NH_2 (SEQ ID NO:3) [etelcalcetide]."

97. Claim 15 of the '712 patent covers "[a] method of treating secondary hyperparathyroidism (SHPT) in a subject, comprising administering to the subject a therapeutically effective amount of the salt of claim 8."

98. Upon information and belief, MSN's Proposed ANDA Product is covered by one or more claims of the '712 patent, including at least claims 8 and 15, because it contains a pharmaceutically acceptable salt of etelcalcetide—*i.e.*, etelcalcetide hydrochloride—and will be used in a method of treating secondary hyperparathyroidism.

99. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, will infringe one or more claims of the '712 patent, including at least claims 8 and 15, either literally or under the doctrine of equivalents.

100. Upon information and belief, MSN filed as part of ANDA No. 215877 a Paragraph IV Certification, asserting that the claims of the '712 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product.

101. MSN did not contend in its Notice Letter that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe claims 1-5 and 7-17 of the '712 patent.

102. MSN has no reasonable basis to believe that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe one or more valid claims of the '712 patent.

103. The purpose of filing ANDA No. 215877 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product prior to the expiration of the '712 patent.

104. MSN's submission of ANDA No. 215877 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product prior to the expiration of the '712 patent is an act of infringement of the '712 patent under 35 U.S.C. § 271(e)(2)(A).

105. Upon information and belief, MSN intends to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto, *i.e.*, prior to the expiration of the '712 patent.

106. Upon information and belief, MSN has knowledge of the '712 patent at least because the '712 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, MSN continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto.

107. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '712 patent when ANDA No. 215877 and any amendments thereto are

approved, and will do so with specific intent to induce infringement of the '712 patent. Further upon information and belief, MSN plans and intends to, and will, do so immediately and imminently upon approval.

108. Upon information and belief, MSN knows that MSN's Proposed ANDA Product is especially made or adapted for use in infringing the '712 patent, and that MSN's Proposed ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, MSN plans and intends to, and will, contribute to infringement by others of the '712 patent immediately and imminently upon approval of ANDA No. 215877 and any amendments thereto.

109. The foregoing actions by MSN constitute and/or will constitute infringement of the '712 patent, active inducement of infringement of the '712 patent, and contribution to the infringement by others of the '712 patent, either literally or under the doctrine of equivalents.

110. Unless MSN is enjoined from infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to infringement by others of the '712 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V
(Infringement of the '938 Patent)

111. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

112. Claim 1 of the '938 patent covers "[a] pharmaceutical formulation comprising AMG 416 [etelcalcetide] in aqueous solution, wherein the formulation has a pH of 2.0 to 5.0."

113. Upon information and belief, MSN's Proposed ANDA Product is covered by one or more claims of the '938 patent, including at least claim 1, because it is a pharmaceutical formulation comprising etelcalcetide in an aqueous solution having a pH of 2.0 to 5.0.

114. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product

in accordance with and as directed by MSN's proposed labeling for that product, will infringe one or more claims of the '938 patent, including at least claim 1, either literally or under the doctrine of equivalents.

115. Upon information and belief, MSN filed as part of ANDA No. 215877 a Paragraph IV Certification, asserting that the claims of the '938 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of MSN's Proposed ANDA Product.

116. MSN did not contend in its Notice Letter that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe the claims of the '938 patent.

117. MSN has no reasonable basis to believe that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe one or more valid claims of the '938 patent.

118. The purpose of filing ANDA No. 215877 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product prior to the expiration of the '938 patent.

119. MSN's submission of ANDA No. 215877 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product prior to the expiration of the '938 patent is an act of infringement of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

120. Upon information and belief, MSN intends to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto, *i.e.*, prior to the expiration of the '938 patent.

121. Upon information and belief, MSN has knowledge of the '938 patent at least because the '938 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, MSN continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto.

122. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '938 patent when ANDA No. 215877 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '938 patent. Further upon information and belief, MSN plans and intends to, and will, do so immediately and imminently upon approval.

123. The foregoing actions by MSN constitute and/or will constitute infringement of the '938 patent and active inducement of infringement of the '938 patent, either literally or under the doctrine of equivalents.

124. Unless MSN is enjoined from infringing the '938 patent and actively inducing infringement of the '938 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI
(Infringement of the '765 Patent)

125. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

126. Claim 1 of the '765 patent covers "[a] pharmaceutical formulation comprising AMG 416 [etelcalcetide] hydrochloride in aqueous solution, wherein the formulation has a pH of 2.0 to 5.0."

127. Upon information and belief, MSN's Proposed ANDA Product is covered by one or more claims of the '765 patent, including at least claim 1, because it is a pharmaceutical formulation comprising etelcalcetide hydrochloride in an aqueous solution having a pH of 2.0 to 5.0.

128. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, will infringe one or more claims of the '765 patent, including at least claim 1, either literally or under the doctrine of equivalents.

129. Upon information and belief, MSN filed as part of ANDA No. 215877 a Paragraph IV Certification, asserting that the claims of the '765 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of MSN's Proposed ANDA Product.

130. MSN did not contend in its Notice Letter that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe the claims of the '765 patent.

131. MSN has no reasonable basis to believe that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe one or more valid claims of the '765 patent.

132. The purpose of filing ANDA No. 215877 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product prior to the expiration of the '765 patent.

133. MSN's submission of ANDA No. 215877 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA

Product prior to the expiration of the '765 patent is an act of infringement of the '765 patent under 35 U.S.C. § 271(e)(2)(A).

134. Upon information and belief, MSN intends to engage in the commercial manufacture, use, sale and/or offer for sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto, *i.e.*, prior to the expiration of the '765 patent.

135. Upon information and belief, MSN has knowledge of the '765 patent at least because the '765 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Amgen's Parsabiv® (etelcalcetide) drug product. Notwithstanding this knowledge, MSN continues to assert its intent to engage in the manufacture, use, offer for sale, and/or sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 215877 and any amendments thereto.

136. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '765 patent when ANDA No. 215877 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '765 patent. Further upon information and belief, MSN plans and intends to, and will, do so immediately and imminently upon approval.

137. The foregoing actions by MSN constitute and/or will constitute infringement of the '765 patent and active inducement of infringement of the '765 patent, either literally or under the doctrine of equivalents.

138. Unless MSN is enjoined from infringing the '765 patent and actively inducing infringement of the '765 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that MSN's submission of ANDA No. 215877 to the FDA was an act of infringement of one or more claims of the Asserted Patents;

(b) A judgment that MSN's making, using, offering to sell, selling, marketing, distributing, or importing into the United States MSN's Proposed ANDA Product prior to the expiration of the Asserted Patents will infringe, will actively induce infringement of, and/or will contribute to the infringement by others of one or more claims of the Asserted Patents;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for MSN to make, use, offer for sale, sell, market, distribute, or import MSN's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, be not earlier than the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining MSN, MSN's affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with MSN, from making, using, selling, offering to sell, marketing, distributing, or importing MSN's Proposed ANDA Product, or any product the use of which infringes the Asserted Patents, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the Asserted Patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

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